## REMARKS/ARGUMENTS

Claims 25-27, 29-35, 37-43, 45-51 and 53-66 are pending in this application. Of the pending claims, nos. 25-27, 29-32, 41-43 and 45-48 are rejected, while claims 33-35, 37-40, 49-51 and 53-66 are withdrawn by the Examiner from further consideration in this application as being drawn to non-elected inventions.

For the reasons provided below, all of the pending claims are cancelled in this response and replaced with a new set of claims numbered 67-74. These claims are all supported by the application as originally filed and thus they raise no issue of new matter. Entry of the new claims into the file of the application is, therefore, respectfully solicited.

## ELECTION/RESTRICTIONS AND SUBMISSION OF NEW CLAIMS

In an Office Action issued December 31, 2008 the Examiner issued a 14-way restriction of the claims filed with this application. In their response filed on January 29, 2009 the applicants elected, with traverse, Group I (claims 25-32). Certain of the claims were amended and applicants argued in their traversal that, as amended, the claims of Groups I, II, III and IV all contain a single special technical feature linking them together such that the claims of those groups should all be examined together in the present application.

Thereafter, in the Office Action dated April 24, 2009 the Examiner responded to applicants' traversal and agreed to examine the claims of Group III together with those of Group I. Otherwise, however, the remainder of the restriction was made Final.

Applicants, nevertheless, incorporated a "Request for Reconsideration Re: Restriction Requirement" in their Response filed June 25, 2009 to the April 24th Office Action. Applicants' request contended that the Examiner had construed the special technical feature too narrowly, i.e., the feature should be taken to include two aspects, namely: (1) that the claimed agent comprises, as the only active component, at least one material selected from the group consisting of (C1 – C20) dialkyl ketone peroxides and all of their possible isomers; and (2) that the active component is present in a percentage by volume of less than or equal to 5%. Applicants thus argued that the special technical feature includes both of the above-described aspects and that therefore the restriction of Groups II and IV from Groups I and III should be withdrawn.

Thereafter, however, in the most recent Office Action issued in this case, i.e., dated November 9, 2009, the Examiner stated that applicants' arguments against the restriction

requirement were not found to be persuasive for the reasons cited in the previous Office Action and that the restriction requirement of Groups II and IV – XIV is still deemed proper and is therefore made final.

The claims of Group I and Group III joined by the Examiner for consideration in the present application were directed, respectively, to a method for sterilizing (Group I) and a method for disinfecting (Group III). According to the Examiner (see, e.g., p. 3 of the April 24, 2009 Office Action) "disinfecting" and "sterilizing" are often used as synonymous terms and art found on sterilizing an object would also read on disinfecting an object.

Taking the above discussion into account, applicants propose herein to cancel without prejudice or disclaimer all of the presently pending claims (including those under examination and those that have been withdrawn) and to replace them with a set of new claims numbered 67 – 74, directed to a biocidal method for at least partially reducing the presence of harmful and damaging organisms from a surface. As by the method recited in the proposed new claims surfaces would be disinfected/sterilized, applicants respectfully submit that the claims are directed to the same invention which is presently under examination and thus entry, and consideration, of the proposed new claims into the file of the present application is respectfully requested. The remarks which follow below are provided to explain applicants' strategy in submitting the proposed new claims.

Generally speaking, the present inventors are concerned with the development of a composition able to at least partially reduce the presence of harmful and damaging organisms from a surface. Depending upon the result achieved upon treatment of such surface(s), applicants have arbitrarily defined such methods of treatment as a "disinfecting" treatment, an "antiparasitic" treatment, etc.

Thus, with regard to the restriction of applicants' as-filled claims into, *inter alia*, Groups I – IV, applicants respectfully submit that they believe that the classification of the method taught in the present application into a separate "sterilizing method", a separate "aseptic method", a separate "disinfecting method" and a separate "deparasitizing method" is, in essence, an artificial distinction, i.e., a distinction without any real difference. This is because the technical effect achieved with the use of applicants' claimed composition consisting essentially of a compound selected from (C1 – C20) dialkyl ketone peroxides clearly depends not on the composition as claimed, but on the type of harmful organism present on the surface to be treated.

More specifically, the inventors have found that treating an object surface, animal or human skin, and/or human or animal mucosal surface with a composition consisting essentially of (C1 – C20) dialkyl ketone peroxide at a percentage by volume less than or equal to 5% eliminates or at least reduces the presence of harmful or damaging organisms present on the object surface. A variety of such harmful or damaging organisms are taught in the present application, including bacteria, viruses, fungi, spores, protozoa, algae, parasites and insects. Furthermore, the specification includes examples demonstrating the effect of the claimed composition on bacteria, fungi, spores, viruses and mycobacteria. Thus, whether the treatment is characterized as antibacterial, antifungal, insecticidal, etc. simply depends on which damaging organisms are to be eliminated. As noted above it has nothing to do with the composition, i.e., the composition is the same in all cases. Thus, as indicated above applicants believe that the distinctions among the various independent claims of Groups I – IV that were previously presented are, in fact, artificial and not real distinctions at all.

Applicants submit that the term "biocidal" encompasses all of the previous artificial distinctions and thus the presently proposed claims, i.e., 67 – 74, are directed to a "biocidal" method for at least partially reducing the presence of harmful and damaging organisms from a surface. The term "biocidal" is supported in the application as originally filed in, e.g., the title, in the Field of the Invention (p. 1) and in paragraphs [0032] and [0038] of the published U.S. application (No. 2007/0112062) and thus the use of the term in the new set of claims submitted herein by the applicants is believed to be entirely justified due to the wide spectrum of activity, i.e., in terms of the 'type' of organism which is reduced or eliminated, offered with the use of the presently claimed method.

For the reasons submitted above, therefore, the Examiner is respectfully requested to enter and consider the patentability of the new claims provided herein. These claims are all directed, in applicants' view, to a single invention which applicants believe is not distinct from the invention that already is under examination.

**Rejections of the Previous Claims Under 35 U.S.C. §103**

On p. 4 of the present Office Action claims 25-27, 29-32, 41-43 and 45-48 are rejected under 35 U.S.C. 103 as being allegedly unpatentable over Jimenez EP 0 775 439 in view of Krezanoski USP 3,852,210. Applicants recognize that the claims as presented herein are not the

same as those rejected by the Examiner. Nevertheless, the following remarks are provided for the purpose of establishing how the presently presented claims distinguish over the cited combination of references. That is, the following remarks consider that the pending claims are nos. 67 – 74 and not those that were previously pending prior to submission of the present response.

The Office Action alleges that one having at least an ordinary level of skill at the time the present invention was made would have been motivated to use (C1 – C20) dialkyl ketone peroxides at less than 5% by volume due, at least in part, to the fact that Krezanoski teaches that exemplary suitable active oxygen yielding compounds, including methyl ethyl ketone peroxide, are used in amounts of preferably 0.5 – 10% to produce stable formulations. The Office Action, moreover, goes on to indicate the Examiner's view that such a skilled artisan also would have been motivated to use a volume concentration of the (C1 – C20) dialkyl ketone peroxides of less than or equal to 5% as a matter of "routine experimentation". According to the Action one skilled in the relevant art would have been motivated by the disclosure found in Jimenez to use less of the active component with a reasonable expectation of success in order to optimize the results thus obtained with the use of such lesser amount.

Applicants respectfully disagree with the position as outlined in the Office Action. To begin with, Jimenez is concerned with the use of a (C1 – C6) dialkyl ketone peroxide at 12-70% for the preservation of dead tissue. In applicants' opinion, Krezanoski is not teaching (or suggesting) the use of (C1 – C20) dialkyl ketone peroxides, including the claimed methyl ethyl ketone peroxide ("MEKP"), at less than 5%. Krezanoski teaches the use in a concentrate composition of a wide list of active oxygen yielding compounds in amounts ranging from 0.1 to 50%, preferably 0.1 – 10%, exemplifying only urea peroxide, benzoyl peroxide and hydrogen peroxide, which is also the preferred active oxygen yielding compound according to the reference (col. 2, line 28).

Krezanoski, moreover, at col. 2 line 35, recites a list of examples of suitable active oxygen yielding compounds; however, the reference does not specifically disclose the use, on animal or human skins, or mucosal surfaces, of (C1 – C20) dialkyl ketone peroxides, such as MEKP, at a concentration of 5% or less.

Thus, in light of the above, applicants submit that one having at least an ordinary level of skill in this art wishing to provide a biocidal method suitable for use on any kind of surface,

including human or animal skin or mucosal surfaces, it would not have been obvious to use the composition according the presently submitted claims by virtue of the combined disclosure of Jimenez and Krezanoski since, even after combining the subject references, the skilled artisan would still have to choose the claimed range of less than or equal to 5% by volume as well as the specific active oxygen yielding compounds recited for use in the present claims, i.e., (C1 – C20) dialkyl ketone peroxides, including MEKP.

Further to the above, the Examiner's attention is respectfully directed to the fact that at the time the present invention was made general understanding in the art was that MEKP was very toxic and a severe irritating agent. This, thus provided a teaching away from the use of MEKP and/or other members of the (C1 – C20) dialkyl ketone peroxides for application to surfaces of living tissue. This is why the Jimenez reference teaches the use of MEKP at high concentrations, i.e., of between 12% and 70% on dead tissue and why the Krezanoski reference, as stated above, does not disclose the use of the compositions as recited in applicants' claims on human or animal skin or mucosal surfaces.

The present inventors, however, notwithstanding the attitude in the prior art regarding the toxic and irritating effect of relatively high levels of the claimed active component, surprisingly discovered that compositions comprising as an active ingredient a (C1 – C20) dialkyl ketone peroxide, such as MEKP, in a percentage by volume less than 5% are unexpectedly effective in reducing the presence of harmful and damaging organisms from surfaces as claimed, and that these materials are not harmful either to human health or the environment.

A demonstration of the unexpectedly non-toxic nature of the presently claimed composition i.e., in the concentration as recited in the claims, is provided in a journal article by J. Garcia-de-Lomas, et al. entitled, "Evaluation of the in-vitro cidal activity and toxicity of a novel peroxygen biocide: 2-butanone peroxide" published in Journal of Hospital Infection (2008) 68, pp. 248-254. A copy of the article is submitted herewith for the convenience of the Examiner. The Examiner is respectfully invited to consider the article, including its evidence that in the concentration(s) recited in the claims, applicants claimed compositions are both safe and effective for their intended purpose, in contrast to what was understood in the prior art.

The article is, furthermore, listed on the form also attached at the end of this response. The Examiner is respectfully requested to make the article of record in this application. A fee of

$180.00 is believed to be due for making the reference of record and credit card payment of the required fee is being submitted via EFS – Web.

Based on the arguments presented above, therefore, and as supported by the contents of the attached Journal of Hospital Infection article, the Examiner is respectfully requested to reconsider and withdraw the rejection under §103 of applicants' claims based on the combination of Jimenez and Krezanoski.

Further to the above, in the pending Office Action claims 25-27 and 41-43 (now replaced with proposed new claims 67-74) were rejected under 35 U.S.C. §103 over Brankling (WO 97/47708) in view of Krezanoski (USP 3,852,210). The Examiner is, in response, respectfully requested to consider the following points as they apply to the new claims submitted herewith.

The Brankling reference discloses a method for reducing the souring of hydrocarbons due to bacterial production of hydrogen sulphide gas. It teaches the use of peroxy compounds for treating bacterially contaminated reservoirs (thus obviating any worry with regard to the toxicity and/or irritating effect – discussed above – of the active component). Brankling further teaches that peroxy compounds generate free radicals, which are aggressive against contaminant living cells, and which ultimately destroy the contaminating cells. Brankling, furthermore, teaches the use of MEKP. The Office Action notes that the reference does not teach the claimed percentage by volume of the active component, and thus the reference is combined with Krezanoski which, as noted above, is believed by the Examiner to provide the missing aspect of applicants' composition as claimed.

Furthermore, the finding by the Examiner of *prima facie* obviousness and the rationale for combining the subject references is essentially the same as that noted for the combination of Jimenez with Krezanoski (discussed above).

Applicants respectfully traverse the conclusions set forth in the Office Action. The composition as recited in the presently presented claims is adapted for use in a biocidal method on, e.g., human and animal skin and mucosal surfaces. One having at least an ordinary level of skill in this art who is knowledgeable with regard to the toxicity of MEKP yet who wishes to engage in such a biocidal treatment of, e.g., such human and/or animal skin or mucosal surfaces, would not have been motivated to consider the teachings contained in Brankling, which teaches instead the treatment (only) of inert surfaces, i.e., such as the bacterially contaminated reservoirs mentioned above. Even if such a skilled individual did choose, for whatever reason, to consider

the teachings of Brankling, applicants note that the subject reference is entirely silent with regard to the use of the active component on humans and/or animals (i.e., due to its toxicity and its tendency to cause irritation as noted above) and is, as well, silent with regard to any particular range of the active component.

In applicants' opinion the Krezanoski reference does not teach the use of (C1 – C20) dialkyl ketone peroxides – including MEKP – at a concentration of less than or equal to 5% by volume. As stated above the subject reference teaches a wide variety of active oxygen yielding compounds in amounts ranging from 0.1 – 50%, preferably 0.1 – 10% and provides examples of only urea peroxide, benzoyl peroxide and hydrogen peroxide, the last of which is the preferred oxygen-yielding compound according to the subject reference. The reference, furthermore, does not disclose the use on animal or human skin, or mucosal surfaces, of (C1 – C20) dialkyl ketone peroxides, such as MEKP, at concentrations at or below 5% by volume.

It is, therefore, submitted that one of ordinary skill in this art would not find themselves motivated to provide the present composition in light of the combined disclosure of Brankling and Krezanoski for use in a biocidal method applicable to, *inter alia*, human and animal skin and mucosal surfaces. The skilled individual would additionally have in their mind, as mentioned above, the prejudice against the use of the claimed materials due to the toxicity and tendency towards causing irritation attributable to the application of compositions comprising greater than the amount of the active component recited in applicants' claims.

Based on the remarks provided herein, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §103 of applicants' claims based on the combination of Brankling and Krezanoski.

**Summary**

The proposed new claims are believed to entirely distinguish applicants' method from the cited prior art. If the Examiner does not agree, however, but believes that an interview would advance the progress of this application, she is respectfully invited to telephone applicants' representative at the number below so that an interview may be scheduled.

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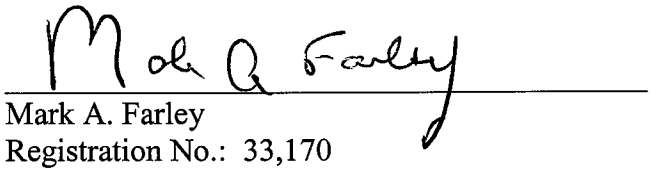
Respectfully submitted,



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